

PATENT
P-4523/15

COMMENTS

Introduction

Applicants have amended claim 1 to recite further aspects of the invention, as described, for example, in paragraph 0008 and as shown in Fig. 1.

Objections to Drawings

The Examiner objected to the drawings because the two sketches labeled Fig. 2 created some confusion.

Applicants have included a replacement sheet that shows the invention as described, as recited in claim 5, and as shown in the original drawings.

Claim Rejections

A. Claims 1, 2 and 4-6 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,591,138 to Vaillancourt ("Vaillancourt") in view of U.S. Patent No. 6,322,540 to Grabis et al. ("Grabis").

B. Claim 3 was rejected under § 103(a) as being unpatentable over Vaillancourt and Grabis, and further in view of U.S. Patent No. 5,779,679 to Shaw ("Shaw").

The rejections are respectfully traversed.

As amended, claim 1 recites a needle assembly having, among other things, a hub having an inner tube and an outer tube connected to each other, arranged such that a cylindrical space is defined between them, with a cannula connected to the inner tube. A shield is telescoped in the cylindrical space, the shield having a deflectable finger with an actuator engaging and projecting through a retaining aperture in the outer tube. A spring is disposed between the shield and the hub for urging the shield to a distal position, upon displacement of the actuator from the retaining aperture. In an initial state of the needle assembly, the cannula is at least partially exposed, the shield is located in a proximal position that allows such exposure, and the cannula has a safety cap disposed over at least a portion thereof.

The cited references do not render amended claim 1 obvious.

PATENT
P-4523/15

First, there would have been no motivation to combine the references in the manner asserted by the Examiner. Vaillancourt and Grabis have different and conflicting techniques for shielding a needle. Specifically, Vaillancourt begins with its shield extending over the needle, whereas Grabis begins with an exposed needle. Vaillancourt requires a two-handed twisting technique to operate the device, whereas Grabis is a one-handed push technique. Vaillancourt has inner and outer tubes with a shield located between, whereas Grabis has an inner tube with a shield located around that tube, i.e., there are only 2 concentric components. In Vaillancourt, the actuator is part of the shield (see Fig. 15), whereas in Grabis, the button is a separate component that is secured to the inner tube/hub. And in Vaillancourt, the activator never moves internal to the outermost tube, whereas in Grabis the activator must be pushed internal to the outermost tube for activation.

For these reasons, applicants submit that one seeking to improve Vaillancourt would not look to Grabis. There is no suggestion in either to combine them, and in fact it is not clear how one would even do so and still retain an operative device. In addition, Vaillancourt itself discloses a solution if a user desired more or better control, which is the solution of Fig. 15. The combination is therefore not supported by either reference.

Second, even the asserted combination of the references would not have led one skilled in the art to the claimed invention. If one incorporated the button of Grabis into Vaillancourt, as asserted by the Examiner, the result would not disclose or suggest the claimed invention. For example, the overall goal of Vaillancourt is to begin with a shielded device temporarily locked in place, allow the user to un-shield the needle for use – again temporarily locked in place, and then allow the user to controllably re-shield. The device resulting from a combination would therefore begin in the shielded configuration disclosed by Vaillancourt, would allow a temporary locking in that shielded configuration, would allow a user to retract and temporarily lock the shield, and would allow a user to then release the shield to re-cover the needle.

Such a device does not read on the claimed invention, in particular the recitations of the initial state being one where the needle is exposed, and of the presence of a safety cap over the exposed needle in this initial state. Moreover, use of an initially exposed needle and safety cap goes against the overall goal of Vaillancourt. Thus, to reach the

PATENT
P-4523/15

present invention, one skilled in the art would have to abandon the goal and purpose of Vaillancourt. But there is no motivation to do so. And modification of a reference in a manner that destroys its function cannot support an obviousness rejection.

For this reason, even a combination of the references would not lead to the invention of amended claim 1.

As for Shaw, it does not provide any disclosure that would otherwise motivate one to completely ignore the goal and purpose of Vaillancourt. As it's activation mechanism is very different from a push button, it is properly relied upon only for the concept that wingsets can be designed with safety features.


For these reasons, applicants submit that the cited references do not render amended claim 1 obvious.

In view of the amendments and remarks above, applicants respectfully request reconsideration of the application, and allowance of all claims.

If there are any additional fees related to this Amendment, such fees should be charged to Deposit Account No. 02-1666.

Respectfully submitted,

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